UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SHIRE LLC,	:	
	:	
Plaintiff,	:	**07 Civ. 3526 (MGC)**
	:	
v.	:	
	:	
TEVA PHARMACEUTICAL INDUSTRIES LTD. and TEVA PHARMACEUTIICALS USA, INC.,	:	
	:	
Defendant.	:	
	:	

TEVA PHARMACEUTICAL INDUSTRIES LTD.'S ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFF'S AMENDED COMPLAINT

Defendants Teva Pharmaceutical Industries Ltd. ("Teva Ltd."), through its undersigned counsel, as and for its Answer, Defenses, and Counterclaims to the Complaint by Shire LLC ("Plaintiff"), responds as follows:

The Parties

1. Shire is a corporation organized and existing under the laws of the State of Kentucky, having its principal place of business at 9200 Brookfield Court, Florence, Kentucky 41042.

ANSWER: Teva Ltd. lacks sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 1 of the Complaint and therefore denies the same.

2. Defendant Teva Ltd. is a corporation organized and existing under the laws of Israel, having its principal place of business at 5 Basel Street, Petach Tikva 49131, Israel.

ANSWER: Admitted.

3. Defendant Teva USA is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454-1090.

ANSWER: Admitted.

4. Teva USA is a wholly-owned subsidiary of Teva Ltd.

ANSWER: Teva Ltd. admits that Teva Ltd. owns 100% of the ownership and voting interest in Teva USA and, except as so admitted, deny the allegations of paragraph 4 of the Complaint.

5. Unless otherwise stated, Teva Ltd. And Teva USA will be referred to collectively as "Teva."

ANSWER: Teva Ltd. admits that Plaintiff collectively refers to Teva Ltd. and Teva USA as "Teva".

Nature of the Action

6. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, involving United States Patent No. 5,326,570 ("the '570 patent"); Exhibit A hereto.

ANSWER: Teva Ltd. admits that this is an action for patent infringement under the patent laws of the United States, Title 35, United States Code in which Shire asserts claims of the '570 patent.

Jurisdiction and Venue

7. This Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Paragraph 7 of the Complaint states a legal conclusion to which no response is required.

8. Upon information and belief, Teva Ltd. conducts business throughout the United States and specifically within New York.

ANSWER: Teva Ltd. denies the allegations of paragraph 8 of the Complaint.

9. This Court has personal jurisdiction over Teva Ltd. because Teva Ltd. maintains sufficient minimum contacts, both generally and specifically, with this judicial district. The exercise of such jurisdiction is consistent with the requirements of due process and does not offend traditional notions of fair play and substantial justice.

ANSWER: Paragraph 9 of the Complaint states a legal conclusion to which no response is required.

10. Upon information and belief, Teva USA regularly conducts business throughout the United States and specifically derives substantial revenue from goods, food, services, or manufactured products used or consumed in New York, including but not limited to sales and distribution of drugs.

ANSWER: Teva Ltd. admits that Teva USA regularly conducts business throughout the United States, including New York, and derives revenue from the sale and distribution of pharmaceutical products. Teva Ltd. denies the remaining allegations of paragraph 4 of the Complaint.

11. This court has personal jurisdiction over Teva USA because Teva USA maintains sufficient minimum contacts, both generally and specifically, with this judicial district. The exercise of such jurisdiction is consistent with the requirements of due process and does not offend traditional notions of fair play and substantial

justice.

ANSWER: Paragraph 11 of the Complaint states a legal conclusion to which no response is required.

12. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

ANSWER: Paragraph 12 of the Complaint states a legal conclusion to which no response is required.

Background

13. Shire is the owner of New Drug Application ("NDA") No. 20-712, which was approved by the Food and Drug Administration ("FDA") for the manufacture and sale of an extended-release capsule containing carbamazepine for the treatment of epilepsy and trigeminal neuralgia. Shire US, Inc. (a related company) markets and sells these compositions in the United States under the trade name Carbatrol®.

ANSWER: Teva Ltd. admits that NDA No. 20-712 was approved by the FDA for the manufacture and sale of an extended-release capsule containing carbamazepine for the treatment of epilepsy and trigeminal neuralgia. Teva Ltd. admits, on information and belief, that Shire US, Inc. markets and sells a carbamazepine product under the trade name Carbatrol®. Teva Ltd. denies the remaining allegations of paragraph 13 of the complaint.

14. Upon information and belief, Teva USA submitted Abbreviated New Drug Application ("ANDA") No. 78-592 ("Teva's ANDA") to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, and sale of carbamazepine

extended-release capsules at the 100 mg, 200 mg, and 300 mg dosage strengths ("Teva's ANDA Products").

ANSWER: Admitted.

15. Teva USA sent Shire a "Patent Certification Notice -- U.S. Patent Nos. 5,326,570 and 5,912,013" pursuant to § 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)(2)(B)), dated March 20, 2007 ("Teva's Notice Letter" or "Notice Letter").

ANSWER: Admitted.

16. Upon information and belief, Teva Ltd. directed Teva USA to file ANDA No. 78-592, and Teva USA complied. Teva Ltd. also directed Teva USA to submit paragraph IV certifications concerning the '570 patent, and Teva USA also complied.

ANSWER: Teva Ltd. admits that Teva USA filed ANDA No. 78-592. Teva Ltd. also admits that Teva USA submitted paragraph IV certification concerning the '570 patent. Teva Ltd. denies the remaining allegation of paragraph 16 of the Complaint.

17. Upon information and belief, Teva Ltd. and Teva USA were both aware of the '570 patent when Teva Ltd. directed Teva USA to file ANDA No. 78-592 and submit paragraph I'V certifications concerning the '570 patent.

ANSWER: Teva Ltd. admits that Teva Ltd. and Teva USA were aware of the '570 patent when Teva USA filed ANDA No. 78-592 and submitted paragraph I'V certifications concerning the '570 patent. Teva Ltd. denies the remaining allegations of paragraph 17 of the Complaint.

18. Upon information and belief, Teva Ltd. directed Teva USA to send Shire the Notice Letter and Teva USA complied.

ANSWER: Teva Ltd. admits that Teva USA sent Shire the Notice Letter but denies the remaining allegations of paragraph 18 of the Complaint.

FIRST COUNT
(Infringement of the '570 Patent)

19. Shire repeats and realleges paragraphs 1 through 18 above as if fully set forth herein.

ANSWER: Teva Ltd. reasserts and incorporates by reference each of the answers to paragraphs 1 through 18 above, as if fully set forth herein.

20. The '570 patent, entitled "Advanced Drug Delivery System And Method Of Treating Psychiatric, Neurological And Other Disorders With Carbamazepine," was duly and legally issued on July 5, 1994, to Pharmavene, Inc. ("Pharmavene") upon assignment from Edward M. Rudnic and George W. Belendiuk. Upon Pharmavene's merger with and into Shire Laboratories Inc. ("Shire Laboratories"), Shire Laboratories became the owner of the '570 patent. Upon the merger of Shire Laboratories into Shire, Shire became and remains the owner of the '570 patent. The '570 patent claims, *inter alia,* a drug delivery system for the oral administration of carbamazepine.

ANSWER: Teva Ltd. admits that the '570 patent, entitled "Advanced Drug Delivery System And Method Of Treating Psychiatric, Neurological And Other Disorders With Carbamazepine," issued on July 5, 1994. Teva Ltd. also admits that the '570 patent identifies the inventors as Edward M. Rudnic and George W. Belendiuk, and the assignee as Pharmavene, Inc. ("Pharmavene"). Teva Ltd. does not have sufficient knowledge to form a belief as to the chain of ownership of the '570 patent. Teva Ltd. also denies that paragraph 20 accurately describes what the '570

patent claims. Teva Ltd. denies the remaining allegations in paragraph 20 of the Complaint.

21. Pursuant to 21 U.S.C. § 355(b)(1), the '570 patent is listed in "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") as covering Shire's Carbatrol® drug products.

ANSWER: Admitted.

22. Upon information and belief, Teva USA filed a paragraph IV certification for the '570 patent in its ANDA to obtain approval to engage in the commercial manufacture, use or sale of carbamazepine extended-release capsules before the expiration of the '570 patent.

ANSWER: Admitted.

23. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(6) requires a paragraph IV notification to include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." *Id.*

ANSWER: Teva Ltd. denies that paragraph 23 is a full and accurate description of 21 USC § 355(j)(2)(B) and 21 C.F.R. § 314.95. Teva Ltd. admits 21 U.S.C. § 355(j)(2)(B)(iv)(II) states that a notice is to "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Teva Ltd. admits that 21 C.F.R. § 314.95(c)(6) states that the contents of the notice are to include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." Teva Ltd. also admits the detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

24. On information and belief, as of the date of Teva's Notice Letter (March 20, 2007), Teva was aware of the statutory provisions and regulations referred to in paragraph 23, above.

ANSWER: Admitted.

25. Teva's Notice Letter stated that Teva's ANDA does not infringe the '570 patent. Nevertheless, Teva's Notice Letter provided Shire with insufficient information regarding Teva's ANDA Products that are the subject of ANDA No. 78-592. Until Shire receives sufficient information from Teva, Shire cannot evaluate, confirm or test the correctness of Teva USA's certification that the '570 patent has not and would not be infringed. On information and belief, therefore, Shire alleges that Teva USA's submission to the FDA of ANDA No. 78-592 with a paragraph IV certification for the

'570 patent and for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of a drug product before the expiration of the '570 patent is an act of infringement of one or more claims of the '570 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Teva Ltd. admits that Teva USA's Notice Letter stated that Teva USA's ANDA does not infringe the '570 patent. Teva Ltd. also admits that Shire "alleges" that Teva USA's submission to the FDA of ANDA No. 78-592 with a paragraph IV certification for the '570 patent is an act of infringement of one or more claims of the '570 patent under 35 U.S.C. § 271(e)(2)(A). However, Teva Ltd. specifically denies that the submission of ANDA No. 78-592 with a paragraph IV certification for the '570 patent is an act of infringement of one or more claims of the '570 patent under 35 U.S.C. § 271(e)(2)(A). Teva Ltd. also denies the remaining allegations in paragraph 25 of the Complaint.

26. On information and belief, Shire alleges that Teva's commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed drug products that are the subject of ANDA No. 78-592, carbamazepine extended-release capsules at the 100 mg, 200 mg, and 300 mg dosage strengths, will infringe one or more claims of the '570 patent.

ANSWER: Teva Ltd. admits that Shire "alleges" that Teva's commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed drug products that are the subject of ANDA No. 78-592, carbamazepine extended-release capsules at the 100 mg, 200 mg, and 300 mg dosage strengths, will infringe one or more claims of the '570 patent. However, Teva Ltd. specifically

denies that any commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed drug products that are the subject of ANDA No. 78-592 will infringe one or more claims of the '570 patent.

27. Upon information and belief, Teva has been aware of the existence of the '570 patent, making the acts of infringement set forth above deliberate and willful, thus rendering this case "exceptional" under 35 U.S.C. § 285.

ANSWER: Teva Ltd. admits that Teva USA and Teva Ltd. were aware of the existence of the '570 patent prior to the submission of ANDA No. 78-592. Teva Ltd. denies the remaining allegations of paragraph 28 of the Complaint.

28. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Teva is preliminarily and permanently enjoined by this Court.

ANSWER: Teva Ltd. denies the allegations in paragraph 28 of the Complaint.

RESPONSE TO PRAYER FOR RELIEF

Teva Ltd. denies that Plaintiff is entitled to any relief whatsoever, let alone the relief requested in their Prayer for Relief.

AFFIRMATIVE DEFENSES

First Affirmative Defense

Teva Ltd.' making, using, selling, importation of, or offering to sell the Teva ANDA products in the United States will not infringe any valid and enforceable claim of the '570 patent.

Second Affirmative Defense

In the event that Teva Ltd. is found to infringe any of the claims of the '570 patent, such infringement is not and has not been willful.

Third Affirmative Defense

This Court lacks personal jurisdiction over Teva Ltd. and venue is not proper in this judicial district.

Dated: New York, New York
September 13, 2007

Respectfully submitted,

By: _____

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